

REMARKS

Status of the claims

Claims 1-5 are pending in the present application. Claims 1, 4 and 5 have been amended. Claims 6-10 have been cancelled. No new matter has been added by way of the above amendments.

Rejections under 35 U.S.C. §112, 2nd paragraph

Claims 1 and 5 have been rejected under 35 U.S.C. 112, 2nd paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention. More specifically claims 1 and 5 have been rejected for with the assertion that the limitation “exposing the compound” or “selecting the compound” is unclear. The claims have been amended to clarify the “GABA_A receptor modulator”. Withdrawal of the rejection is respectfully requested.

Rejections under 35 U.S.C. § 103

Claims 1-5 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Kuo-Fen et al. (WO 0105222) in view of Barbaccia. Applicants traverse this rejection and withdrawal thereof is respectfully requested.

The instant invention, as encompassed by claim1, is directed to a method for screening a GABA_A receptor modulator for its potential as a sedative or anxiolytica, by:

- a) exposing the GABA_A receptor modulator to a test animal by administration;
- b) measuring the effect of the GABA_A receptor modulator on the activity of the HPA axis;
- c) selecting the GABA_A receptor modulator as a sedative drug candidate if the compound substantially stimulates the HPA axis or
selecting the GABA_A receptor modulator as an anxiolytica drug candidate if the compound has substantially no effect on the HPA axis.

Kuo-Fen et al. teaches a method for screening for compound having an effect on the response of the hypothalamic- pituitary-adrenal axis (HPA) to stress. The present invention

differs from the teaching of Kuo-Fen et al., in that the compounds have to be modulators of the GABA_A receptor and if the compound substantially stimulates the HPA axis it is selected as a sedative drug candidate and if the compound substantially has no effect on the HPA axis it is selected as an anxiolytica drug candidate.

Barbarccia teaches that modulators of the GABA_A receptors affect the HPA axis and the behavioral correlates of acute stress. Contrary to inhibitors, activators prevent the activation of the HPA axis, i.e. they reduce the plasma and neurosteroid and induce less stress response.

Barbarccia does not teach that a compound, which substantially stimulates the HPA axis, can be selected as a sedative drug candidate and that a compound, which substantially has no effect on the HPA axis, can be selected as an anxiolytica drug candidate. Thus, Barbaccia fails to teach the deficiencies found in Kuo-Fen and as such, the instant invention is not disclosed or suggested by the disclosures of the references. Withdrawal of the rejection is therefore respectfully requested.

In view of the above amendments and Remarks, Applicant believes the pending application is in condition for allowance.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact MaryAnne Armstrong, Ph.D., Reg. No. 40,069 at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.17; particularly, extension of time fees.

Dated: JUL 27 2009

Respectfully submitted,

By 

MaryAnne Armstrong, Ph.D.

Registration No.: 40,069

BIRCH, STEWART, KOLASCH & BIRCH, LLP

8110 Gatehouse Road

Suite 100 East

P.O. Box 747

Falls Church, Virginia 22040-0747

(703) 205-8000

Attorney for Applicant